CONNECTICUT
PHARMACISTS ASSOCIATION

Statement Before:
The Public Health Committee
Monday, March 1, 2010

Re: RB 5307: An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs

Good afternoon Rep. Ritter, Sen. Harris and members of the committee. My name is Marghie Giuliano. I am a pharmacist and the Executive Vice President of the Connecticut Pharmacists Association. The Connecticut Pharmacists Association is a professional organization representing 1000 pharmacists in the state of Connecticut. I am here today to speak in strong opposition of RB 5307: An Act Concerning the Filling of Prescriptions for Antiepileptic Drugs

RB 5307 amends current legislation mandating that a pharmacist cannot substitute an antiepileptic drug for another upon initial filling or refilling without obtaining written permission from the prescriber. It actually creates a separate dispensing process for these medications. There is no clinical evidence that supports the reasoning behind this bill—that changing manufacturers for antiepileptic drugs causes seizures. Carving out this therapeutic class of drugs from the generic substitution laws sets a precedent and creates unnecessary and costly processes that pharmacists, patients, taxpayers and insurance companies absorb.

Due to this, our association has opposed this legislation for the last few years. Prescribers currently have the authority to determine what brand or what generic medication a patient should receive by writing "no substitution" or "brand medically necessary" on the prescription. In years past, we have offered to create a directive in legislation for the prescriber to indicate "no substitution" for generics as well as brand although we believe current legislation allows for this. For example, if a prescriber would like the pharmacist to dispense Teva's brand of Gabapentin then he/she only needs to indicate that on the prescription. Last year we had agreed to compromise language which was eventually rejected by the Epilepsy Foundation.

As medication experts, pharmacists clearly understand the concerns surrounding substituting medications with a narrow therapeutic index. We weigh all the clinical considerations when making a generic determination. Additionally, the language in the bill that includes ICD-diagnoses codes on the prescriptions is helpful in making any generic decisions. However, as we have stated before, there is no scientific evidence to date that demonstrates this therapeutic class of drugs needs to be handled differently than any other medication in the dispensing process. To place unnecessary legislation on pharmacy practice is costly to all.

To this point, the controversy surrounding the therapeutic equivalence of the antiepileptic drugs has caused the Centers for Medicare and Medicaid Services (CMS) to ask the Agency for Healthcare Research and Quality (AHRQ) to conduct an evidence-based assessment of antiepileptic drugs. The purpose is to specifically investigate whether or not there is statistically significant clinical evidence to support allegations that changing manufacturers for antiepileptic drugs causes seizures. AHRQ has asked the UCONN/Hartford Hospital Evidence-Based Practice center to conduct the study. This research is expected to be complete at the end of December 2010.

We strongly urge the committee to wait until this research is completed before passing legislation that may prove to be unnecessary. If the research points to the fact that there is statistically significant clinical evidence that switching medications (brand to generic; generic to generic) causes seizures, CPA will work with you to put forward legislation next session to address it.

In addition, there are two other areas of concern with this legislation; the additional costs to the healthcare system, and most importantly, the impact on the patient. With some of the antiepileptic medications coming off patent, it will be more cost effective for both the patient and the payer to move to generic medications. Setting up barriers to this process is

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counterproductive. Additionally, the language in this legislation does not clearly define how long patients will have to wait for their medications before the prescriber determines if the pharmacist can substitute or change manufacturers of their drug. This too could become a barrier to access and adherence. If the prescriber does not give consent, and the pharmacy is unable to supply the specific product the patient will have to find another pharmacy that has their medication.

This year, HB 5212 AAC Insurance Coverage for the Treatment of Bleeding Disorders, was raised by the Insurance Committee. It also adds a Section 5(i) to Section 20-619 of the general statutes. This bill mandates that pharmacists must obtain authorization from the prescriber before they substitute any medications used for bleeding disorders. As predicted, other brand manufacturers are introducing legislation to "carve out" entire therapeutic classes of drugs from generic substitution laws as well. If a precedent is set, we will see immunosuppressant drugs and drugs for Fibromyalgia looking for the same treatment. Tennessee and Illinois have both seen this progression. Most other states have halted this legislation. This type of legislation is appearing in other states. In reality, it is just a way to protect brand name products from being substituted.

This legislation may not be appropriate for every patient. CPA is certainly sympathetic to patients with epilepsy that are not well controlled. Implementing a protocol-based collaborative practice agreement is the best solution in addressing the needs of this population without disrupting the current dispensing process for everyone.

We strongly urge the committee to oppose this legislation and wait until the research that is being conducted right here in Hartford is completed before passing legislation that may prove to be unnecessary.